UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/711,278	08/22/1996	DAVID J. ANDERSON	A-63770-1/RF	5313

7590 12/17/2001

FLEHR HOHBACH TEST ALBRITTON & HERBERT
FOUR EMBARCADERO CENTER
SUITE 3400
SAN FRANCISCO, CA 94111

EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	36

DATE MAILED: 12/17/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/701,278	Applicant(s) Anderson et al
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 21, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, and 4-7* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, and 4-7* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☒ Interview Summary (PTO-413) Paper No(s). *23*

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 11/21/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/701,278 is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicant's arguments filed 6/21/01 were already fully considered in the Advisory Action of 7/24/01, but they were not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-2 & 4-7 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record in Paper Nos. 26, 29, 33 and as follows.

In contrast to Applicants' assertions on pages 3-7 of the response, the court in *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111, 1117, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention* [emphasis added]". Therefore, in that no known nor described function existed for the DRG11 protein of SEQ ID NO:2, or for polynucleotides that

encoded such, at the time of filing the instant invention, no specific nor substantial utility exists, by definition. For example, *many* proteins, or DNAs that encode such, reasonably are expressed in sensory neurons; especially as it relates to the genus of hybridization products claimed; thereby, not being "specific", by definition. Note further that the claims are not limited to the preferred and described DRG11 polynucleotide sequence of SEQ ID NO:1 (i.e., as it relates to claims 1, 2 & 5-7). Thus, Applicants' arguments remain not persuasive for the reason made of record.

See also the comments from the Advisory Action of 7/24/01 concerning why no specific nor substantial utility exists, since the arguments related to "transcription factors" are not on point. In contrast, the instant invention describes DRG11 as being some "homeodomain protein... in the PHD family", which has no known nor disclosed "regulatory" function, and which, therefore, would reasonably be involved in some unknown and undisclosed protein-protein interaction, versus the protein-DNA interactions that characterize "transcription factors".

Lastly, as previously made of record, further experimentation is still necessary at the time of filing the instant invention to attribute a "real world" utility to the claimed polynucleotides (i.e., as it relates to establishing a "substantial" utility). Again, the rationale is that one would expect that a limited number of dysfunctional genes would be useful as markers for diseases, versus a generalized "molecular marker to identify neurons in the peripheral sensory lineage" or the generalized "markers... [that may be useful] to obtain or isolate pools of such [peripheral

sensory] neurons". Thus, Applicants' arguments remain not persuasive, for the reasons made of record.

5. Claims 1-2 & 4-7 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record in Paper Nos. 26, 29 & 33.

6. Claims 1 & 5-7 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No. 26, 29, 33 and as follows.

In contrast to Applicants' assertions on page 7-8 of the response, the issue remains that one of ordinary skill in the art cannot visualize what generic nucleic acid sequences are specifically encompassed by the current claims (i.e., by SEQ ID NO; as it relates to the undescribed hybridization products claimed); nor could one visualize what constitutes generic sequences encompassed by these claims based solely on the written description of the *single* cDNA sequence of SEQ ID NO:1. Importantly, because no known nor disclosed function exists

for the encoded DRG11 protein(s) of the instant invention, what constitutes a functional allelic variant (i.e., as it relates to the hybridization products claimed) cannot be reasonably determined at the time of filing Applicants' invention, for the reasons made of record.

Accordingly, *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) held that "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". In addition, *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) then held that claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the single species of the encoded rat DRG11 protein of SEQ ID NO:2, and its corresponding DNA of SEQ ID NO:1, has been described in the instant specification. Accordingly,

"[o]ne skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is". *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is directed toward the Revised Interim Utility Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999.

7. Claims 1-2 & 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No proper antecedent basis exists for the recitation "said nucleic acid" because more than one "nucleic acid" is recited in base claim 1; thereby, making it ambiguous as to which "nucleic acid" is being referenced.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
December 6, 2001

Gary L. Kunz

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600